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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/043,877 | 01/09/2002 | Tapas Mukhopadhyay | INRP:095US 10200175 | 6285 |

7590 02/27/2004

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EXAMINER

WEHBE, ANNE MARIE SABRINA

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1632

DATE MAILED: 02/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--|--|--|
| Office Action Summary | Application No. 10/043,877 | Applicant(s) MUKHOPADHYAY ET AL. | |
| | Examiner Anne Marie S. Wehbe | Art Unit 1632 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-182 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-182 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-29, 75-106, 161-162, 164-167, 169-182, drawn to methods of administering a benzimidazole to a cell, classified in class 514, subclass 396.
- II. Claims 30-74, 107-159, 163, 168, drawn to methods of administering tumor suppressor gene therapy comprising administering a vector encoding a tumor suppressor gene and a benzimidazole, classified in class 514, subclass 44.
- III. Claims 107, 163, and 168, drawn to methods of administering a benzimidazole and chemotherapy, classified in class 514, subclass 1.
- IV. Claim 107, 163, 168, drawn to methods of administering a benzimidazole and radiotherapy, classified in class 600, subclass 1.
- V. Claims 107, 163, 168, drawn to methods of administering a benzimidazole and an immunotherapy, classified in class 424, subclass 184.1.
- VI. Claims 107, 163, 168, drawn to methods of administering a benzimidazole and a gene therapy distinct from tumor suppressor gene therapy, classified in class 514, subclass 44.
- VII. Claim 160, drawn to methods of administering a benzimidazole and tumor suppressor gene therapy comprising administering a vector encoding a tumor suppressor gene and chemotherapy, classified in class 514, subclasses 1 and 44.

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- VIII. Claim 160, drawn to methods of administering a benzimidazole and tumor suppressor gene therapy comprising administering a vector encoding a tumor suppressor gene and radiotherapy, classified in classes 514 and 600, subclasses 44 and 1.
- IX. Claim 160, drawn to methods of administering a benzimidazole and tumor suppressor gene therapy comprising administering a vector encoding a tumor suppressor gene and an immunotherapy, classified in classes 514 and 424, subclasses 44 and 184.1.
- X. Claim 160, drawn to methods of administering a benzimidazole and tumor suppressor gene therapy comprising administering a vector encoding a tumor suppressor gene and a gene therapy distinct from tumor suppressor gene therapy, classified in class 514, subclass 44.

Please note that claims 107, 163, and 168 link inventions II-VI, and that claim 160 links inventions VII-X. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 107, 163, and 168, or claim 160. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or

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nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable.

In re Ziegler, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

1) the invention of group I is patentably distinct from the inventions of groups II-X in that benzimidazole compounds/derivatives are made using substantially different techniques, and are structurally, chemically, physically, and functionally different from vectors encoding therapeutic genes, chemotherapeutic compounds, and radiation. As such, the mode of activity of a combination of a benzimidazole and a chemotherapeutic, a gene therapy vector, or radiation is substantially different from the mode of activity of benzimidazole alone.

2) the inventions of groups II-X are patentably distinct in that vectors encoding therapeutic genes, chemotherapeutic compounds, and radiation are substantially different in structural, chemical, physical, and functional properties each from the other, have substantially different modes of operation, and are made using substantially different techniques. Further, vectors encoding a tumor suppressor gene and vectors not encoding a tumor suppressor gene are substantially different in that the functional properties of the vector are determined by the encoded therapeutic polypeptide. Tumor suppressors are a specific class of genes which function in cell cycle inhibitory pathways. Genes which are not tumor suppressors may have any other activity which is clearly different from those of tumor suppressors. As such, the mode of operation of genes which are not tumor suppressors is substantially different from the those of tumor suppressors.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, different classification, and different search requirements, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention.

The inventions of groups II and VII-X, claims 30-74, 107-159, 107, 163, and 168, and claim 160, list the following patentably distinct species of tumor suppressor genes encoded by the vector:

- a) p53
- b) p16
- c) p21
- d) Rb
- e) p15
- f) BRCA1
- g) BRCA2
- h) zac1
- i) p73
- j) ATM
- k) HIC-1
- l) DPC-4

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- m) FHIT
- n) NF2
- o) APC
- p) DCC
- q) PTEN
- r) ING1
- s) NOEY1
- t) NOEY2
- u) PML
- v) OVVA1
- w) MADR2
- x) WT1
- y) 53BP2
- z) IRF-1
- aa) MDA-7
- bb) C-CAM

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 30-39, 42-74, 107-116, 199-159, 163, and 168 are generic.

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Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. The examiner can be reached Monday- Friday from 10:30-7:00 EST. If the examiner is not available, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. For all official communications, the technology center fax number is (703) 872-9306. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Anne M. Wehbé', with a stylized flourish at the end.